PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 1 2 JAN 2006

		WIPO PCT								
Applicant's or agent's file reference SCB 873 PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416								
International application No. PCT/EP2004/011161	International filing date (day/month/year) 06.10.2004	Priority date (day/month/year) 09.10.2003								
International Patent Classification (IPC) or na A61K38/17, C07K14/82	ational classification and IPC									
AUTR36/17, CU/K 14/82										
Applicant INDENA, S.P.A.										
This report is the international prei Authority under Article 35 and tran	liminary examination report, established smitted to the applicant according to Ar	by this International Preliminary Examining ticle 36.								
B. This report is also accompanied by ANNEXES, comprising:										
a. \square sent to the applicant and to the International Bureau) a total of sheets, as follows:										
sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).										
sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.										
b. (sent to the International Bu	b. (sent to the International Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time and any in the international Bureau only) a total of (indicate time any in the international Bureau only) a total of (indicate time any in the international Bureau only) a total of (indicate time any in the international Bureau only) a total of (indicate time any in the international Bureau only) and international Bureau only) a total of (indicate time any international Bureau only) and international Bureau only) and international Bureau only) and international Bureau only) and international Bureau only) are also bureau only and international Bureau only and international Bureau only and any international Bure									
	b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).									
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4 70										
4. This report contains indications rela	ating to the following items:									
Box No. I Basis of the opin	ion									
☐ Box No. II Priority										
☐ Box No. III Non-establishme	ent of opinion with regard to novelty, inve	entive step and industrial applicability								
Box No. IV Lack of unity of ir	nvention									
	Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement									
☐ Box No. VI Certain documen	its cited	statement								
☐ Box No. VII Certain defects in										
☐ Box No. VIII Certain observations on the international application										
Date of submission of the demand	Date of completion	n of this report								
21.07.2005	11.01.2006									
Name and mailing address of the international preliminary examining authority:	Authorized Officer	900-								
European Patent Office	[destruction of the state of the								
D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656	Sepmu d Kalsner, i	olli est								
Fax: +49 89 2399 - 4465	Telephone No. +49	9 89 2399-8708								

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/EP2004/011161

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•	Box No. I	Basis of the repor	rt · ··						
1.	With regar filed, unles	rd to the language , these otherwise indicated	nis report is bas d under this ite	sed on the internat m.	ional application i	n the language in which it was			
	which	eport is based on trai is the language of a	translation furr	nished for the purp	ge into the follow	ing language ,			
	□ pul	ernational search (un blication of the intern ernational preliminan	ational applica	tion (under Rule 12	2.4) and/or 55.3)				
2.	2. With regard to the elements* of the international application, this report is based on <i>(replacement sheets whi have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):</i>								
	Description	n. Pages		e de seguiros					
	1-23	.,	as originally fi	led					
Sequence listings part of the description, Pages									
	1-22		as originally fi	led					
	Claims, Nu	mbers							
	1-13		as originally fi	led					
•	Drawings,	Sheets							
	1/14-14/14		as originally fi	led					
	⊠° a sequ	uence listing and/or a	ny related table	e(s) - see·Supplem	nental Box Relatin	g to Sequence Listing			
3.		mendments have res description, pages	ulted in the car	ncellation of:					
	☐ the	claims, Nos. drawings, sheets/fig:	_						
	☐ the	sequence listing (sp	ecify):	. /					
		table(s) related to s	-						
	had not be	eport has been estab en made, since they ntal Box (Rule 70.2(c)	have been con	me of) the amendr sidered to go beyo	and the disclosure	this report and listed below as filed, as indicated in the			
	☐ the ☐ the	description, pages claims, Nos.				•			
	☐ the	drawings, sheets/figs							
		table(s) related to s		(specify):					
	* If it	em 4 applies, s	ome or all	of these sheet	ts may be mar.	ked "superseded."			

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/EP2004/011161

	∙Во	x No. IV	Lack of unit	y of inventior	າ			•		+ 3 n2+	۶ ٠
1.	. 🗆	☐ restri ☐ paid ☐ paid	onse to the invi icted the claim additional fees additional fees er restricted no	s. s. under protes	t.	dditional	fees, the ap	plicant has:			
2.	⊠	This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.									
3.	Thi	s Authorit	y considers th	at the requirer	ment of un	ity of inve	ention in acc	ordance with	Rules 13.	1, 13.2 and	E.E1 t
		complie	d with.								
	×	not com	plied with for th	ne following re	easons:						
		see sep	arate sheet								
4.	I. Consequently, this report has been established in respect of the following parts of the international application									ation:	
	\boxtimes	all parts.	,								
		the parts	s relating to cla	ims Nos							
		x No. V	Reasoned st	atement und d explanation	er Article ns suppoi	35(2) wit	th regard to h statement	novelty, inv	entive st	ep or indu	strial
1.	1. Statement										
Ordis (1. 13) a	Nov	velty (N)	ander die soor	Yes:" No:	Claims ***	¹⁶⁴ -1413	Turber Strong disk	er for a waring	er star	e mengelejak i en i c	drijkta
	Inve	entive ste	p (IS)	Yes: No:	Claims Claims	1-13					
	Indi	ustrial app	olicability (IA)	Yes: No:	Claims Claims	1-13					
2.	Cita	ntions and	explanations	(Rule 70.7):							
	see	separate	sheet								

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/EP2004/011161

Supp	lemental Box relating to Sequence Listing	
Continua	ation of Box I, item 2:	
1. With renders	egard to any nucleotide and/or amino acid sequence disclosed in the international application and sary to the claimed invention, this report has been established on the basis of:	
a. type	e of material:	
⋈	a sequence listing	
	table(s) related to the sequence listing	
b. form	nat of material:	
⊠.	in written format	
\boxtimes	in computer readable form	
c. time	of filing/furnishing:	
\boxtimes	contained in the international application as filed	
\boxtimes	filed together with the international application in computer readable form	
	furnished subsequently to this Authority for the purposes of search and/or examination	
	received by this Authority as an amendment on	
ade	addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating ereto has been filed or furnished, the required statements that the information in the subsequent or ditional copies is identical to that in the application as filed or does not go beyond the application	

3. Additional observations, if necessary:

Ad Section IV: Lack of unity of invention

The present application does not comply with the requirement of unity as set forth in Art. 34(3) and Rule 13 PCT.

An international application must relate to one invention only or to a group of inventions so linked as to form a <u>single general inventive concept</u>.

Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same special technical features, <u>special</u> technical features being such features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Claim 1 is directed to a DNA transfer vector containing any one of 14 listed DNA sequences.

The technical relationship linking together the different nucleotide sequences (SEQ ID NO: 1-14) can be seen in the fact that they are all encode at least part of the human p185^{neu} protein. As this protein is widely known in the state of the art, this relationship can not be considered novel or inventive. Thus, it cannot be accepted to constitute a special technical feature as defined above as it does not define a contribution which each of the different claimed inventions, considered as a whole, but a makes over the prior art.

Thus, the presently claimed subject-matter falls apart in 14 groups of inventions which are not unitarian, each group consisting of claims 1-13 with respect to each individual nucleic acid sequence.

As search and examination of the present application could be carried out without undue effort, it was chosen not to invite the applicant to restrict or pay additional examination fees.

Ad Section V: Reasoned statement with regard to novelty, inventive step or

industrial applicability

1) Documents

D1...Chen et al. (1998) Cancer Research 58: 1965-1971

D2...Amici et al. (2000) Gene Therapy 7: 703-706

2) Novelty

The present application relates to a DNA vaccines for the prevention or treatment of tumours expressing oncogenes of the ErbB family. The vectors of the present application contain DNA encoding the extracellular domain and the transmembrane domain of human p185^{neu} wherein the extracellular domain may be truncated or replaced by corresponding fragments of the extracellular domain of rat p185^{neu}.

As the sequences as listed in SEQ ID NO: 1-14 have not been disclosed in the prior art as such, the subject-matter of **claims 1-13** is considered to meet the requirements of Art. 33(2) PCT.

3) Inventive step

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The claims, however, do not meet the requirements of Art. 33(3) PCT as the claimed subject-matter does not involve an inventive step.

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Constructs containing the extracellular and transmembrane domains of p185^{neu} both from rat and human have been shown to be suitable for DNA vaccination for preventing or treating tumours (see, e.g, D1 or D2).

The difference between the constructs of the prior art and those claimed in claim 1 seems to lie in the fact that part of each construct is derived from the sequence coding for rat p185^{neu}.

The problem to be solved can be seen in the provision of DNA transfer vectors which

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

PCT/EP2004/011161

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encode chimeric p185^{neu} which enhance the immune response in a patient.

This problem seems to be solved by some constructs as described in the examples and which correspond to Fig. 10-14. For such subject-matter an inventive step could in theory be acknowledged.

The claims, however, are directed to a number of sequences which certainly do not correspond to these constructs of Fig. 10-14 (SEQ ID NO: 1-9). As it is not clear that these constructs actually solve the above indicated problem an inventive step cannot be acknowledged for the current set of claims. It should further be noted that there is no evidence that SEQ ID NO: 10-14 actually do correspond to the plasmid constructs of Fig. 10-14.

Claims 1, 7, 10 and 12 as well as the claims dependent thereon are thus objected to under Art. 33(3) PCT.

Furthermore, **claim 10** is not clear. The wording "combined pharmaceutical preparation" in combination with the terms "sequential or separate therapeutic use" seems to be contradictory. The scope of the claim is thus not clear (Art. 6) PCT.

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